



PTO-SB-08A (08-00)  
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<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> (use as many sheets as necessary) Sheet 1 of 7	<b>Application Number</b>	10/606,575
	<b>Filing Date</b>	June 26, 2003
	<b>First Named Inventor</b>	EDGREN et al.
	<b>Group Art Unit</b>	1615
	<b>Examiner Name</b>	Not yet assigned
	<b>Attorney Docket Number</b>	AR03234

**U.S. PATENT DOCUMENTS**

Examiner Initials	Cite No. <sup>1</sup>	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document mm-dd-yyyy	Pages, Columns, Lines, where relevant passages or relevant figures appear
		Number	Kind Code <sup>2</sup> (if known)			
HA		6,559,293	B1	ALMARSSON et al.	05-06-2003	
		2003/0072802	A1	CUTLER	04-17-2003	
		6,210,712	B1	EDGREN et al.	04-03-2001	
		6,174,547	B1	DONG et al.	01-16-2001	
		5,938,654		WONG et al.	08-17-1999	
		5,614,578		FERRARI et al.	03-25-1997	
		5,413,672		HIROTSUJI et al.	05-09-1995	
		5,391,381		WONG et al.	02-21-1995	
		5,387,700		MARYANOFF et al.	02-07-1995	
		5,340,590		WONG et al.	08-23-1994	
		5,324,280		WONG et al.	06-28-1994	
		5,252,338		JAO et al.	10-12-1993	
		5,190,765		JAO et al.	03-02-1993	
		5,160,743		EDGREN et al.	11-03-1992	
		5,156,850		WONG et al.	10-20-1992	
		5,110,597		WONG et al.	05-05-1992	
		5,082,655		AGARWALA et al.	01-21-1992	
		5,024,842		EDGREN et al.	06-18-1991	
		5,023,088		WONG et al.	06-11-1991	
✓		5,019,397		WONG et al.	05-28-1991	
HA		5,006,346		EDGREN et al.	04-09-1991	

Examiner Signature	<u>HA</u>	Date Considered	4 Sept 2006
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**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet 2 of 7

Application Number	10/606,575
Filing Date	June 26, 2003
First Named Inventor	EDGREN et al.
Group Art Unit	1615
Examiner Name	Not yet assigned
Attorney Docket Number	AR03234

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		Number	Kind Code <sup>2</sup> (if known)			
TH		4,961,932		THEEUWES	10-09-1990	
↑		4,957,494		WONG et al.	09-18-1990	
		4,940,465		THEEUWES et al.	07-10-1990	
		4,931,285		EDGREN et al.	06-05-1990	
		4,915,949		WONG et al.	04-10-1990	
		4,892,778		THEEUWES et al.	01-09-1990	
		4,853,229		THEEUWES et al.	08-01-1989	
		4,824,675		WONG et al.	04-25-1989	
		4,681,583		URQUHART et al.	07-21-1987	
		4,578,075		URQUHART et al.	03-07-1978	
		4,519,801		EDGREN	05-28-1985	
		4,513,006		MARYANOFF et al.	04-23-1985	
		4,327,725		CORTESE et al.	05-04-1982	
		4,207,893		MICHAELS	06-17-1980	
		4,160,020		AYER et al.	07-03-1979	
		4,111,202		THEEUWES	09-05-1978	
		4,111,201		THEEUWES	09-05-1978	
		4,088,864		THEEUWES	05-09-1978	
		4,077,407		THEEUWES et al.	03-07-1978	
		4,008,719		THEEUWES et al.	02-22-1977	
✓		4,002,173		MANNING et al.	01-11-1977	
HA		3,995,631		HIGUCHI	12-07-1976	

Examiner Signature	<i>TH</i>	Date Considered	9/4/06
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Substitute for form 1449A-PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> (use as many sheets as necessary) Sheet 3 of 7	<b>Application Number</b>	10/606,575
	<b>Filing Date</b>	June 26, 2003
	<b>First Named Inventor</b>	EDGREN et al.
	<b>Group Art Unit</b>	1615
	<b>Examiner Name</b>	Not yet assigned
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JH		3,916,899		THEEUWES et al.	11-04-1975	
		3,865,108		HARTOP	02-11-1995	
		3,845,770		THEEUWES et al.	11-05-1974	
		3,546,142		MICHAELS et al.	12-08-1970	
		3,541,006		BIXLER et al.	11-17-1970	
		3,541,005		STRATHMANN et al.	11-17-1970	
		3,276,586		ROSEAN	10-04-1966	
		3,173,876		JACKSON	03-16-1965	
JH		3,133,132		LOEB et al.	05-12-1964	
		2,799,241		WURSTER	07-16-1957	

## FOREIGN PATENT DOCUMENTS

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		Office <sup>3</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup>				
JH		WO	00/72841		Jeffrey Berlant	12-07-2000		
		WO	00/48607	A	Tovama Farmaceutskih et al.	08-24-2000		
		WO	00/25790	A	ALZA Corporation	05-11-2000		
		WO	99/62496	A1	ALZA Corporation	12-09-1999		
		WO	99/44581	A2	Ortho-McNeil Pharmaceutical, Inc.	09-10-1999		
		WO	98/14168	A2	ALZA Corporation	04-09-1998		
JH		WO	98/06380	A2	ALZA Corporation	02-19-1998		

Examiner Signature	<i>[Signature]</i>	Date Considered	9/4/06
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Substitute for form 1449A/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> (use as many sheets as necessary) Sheet 4 of 7	<b>Application Number</b>	10/606,575
	<b>Filing Date</b>	06/26/2003
	<b>First Named Inventor</b>	EDGREN et al.
	<b>Group Art Unit</b>	1615
	<b>Examiner Name</b>	
	<b>Attorney Docket Number</b>	AR03234

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		Number	Kind Code <sup>2</sup> (if known)			
JH ↑         ↓ JH		6,248,363		PATEL et al.	06-19-2001	
		6,569,463		PATEL et al.	05-27-2003	
		2001/0012847	A1	LAM et al.	09-09-2001	
		6,294,192		PATEL et al.	09-25-2001	
		5,906,832		JAO et al.	05-25-1999	
		5,633,011		DONG et al.	05-27-1997	
		5,620,705		DONG et al.	04-15-1997	
		5,262,171		LOGIN et al.	11-16-1993	
		2002/0044960	A1	CHERUKURI	04-18-2002	
		2002/0044962	A1	CHERUKURI et al.	04-18-2002	
		2002/0127196	A1	AVILA et al.	09-12-2002	

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		Office <sup>3</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup>				
JH ↑     ↓ JH		WO	01/37808		PATEL et al.	05-31-2001		
		WO	01/12155		PATEL et al.	02-22-2001		
		WO	98/23263		HOMEL et al.	06-04-1998		
		WO	00/00179		BEOM et al.	01-06-2000		
		WO	99/63971		TALLAUAKHALA	12-16-1999		
		WO	95/06460		ALZA CORPORATION	03-09-1995		
		WO	04/010970	A1	JAO et al.	02-05-2004		

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<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> (use as many sheets as necessary) Sheet 5 of 7	<b>Application Number</b>	10/606,575
	<b>Filing Date</b>	06/26/2003
	<b>First Named Inventor</b>	EDGREN et al.
	<b>Group Art Unit</b>	1615
	<b>Examiner Name</b>	
	<b>Attorney Docket Number</b>	AR03234

**U.S. PATENT DOCUMENTS**

Examiner Initials	Cite No. <sup>1</sup>	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document mm-dd-yyyy	Pages, Columns, Lines, where relevant passages or relevant figures appear
		Number	Kind Code <sup>2</sup> (if known)			
JH		2003/0185882	A1	VERGEZ et al.	10-02-2003	
		2003/0228358	A1	PERLMAN et al.	12-11-2003	
		2004/115262	A1	JAO et al.	06-17-2004	
		2002/0022245	A1	HEBE BRAND et al.	02-21-2002	
		2003/0021841	A1	MATHARU et al.	01-30-2003	
		2004/0053894	A1	MAZESS et al.	03-18-2004	
		4,888,168		POTTS et al.	12-19-1989	
		5,082,655		SNIPES et al.	01-21-1992	
		5,817,321		ALAKHOV et al.	10-06-1998	
		6,562,375	B1	SAKO et al.	05-13-2003	
JH		2005/0053653	A1	KIDANE et al.	03-10-2005	

**FOREIGN PATENT DOCUMENTS**

Examiner Initials	Cite No. <sup>1</sup>	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document mm-dd-yyyy	Pages, Columns, Lines, where relevant passages or relevant figures appear	T <sup>6</sup>
		Office <sup>3</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup>				
JH		WO	02/44276	A2	AVILA et al.	06-06-2002		
		WO	03/002151	A1	MASSIRONI	01-09-2003		
		WO	03/004009	A1	MATHARU et al.	01-16-2003		
		WO	03/011204	A2	CHERUKURI	02-13-2003		
		WO	03/011205	A2	CHERUKURI et al.	02-13-2003		
		WO	03/039519	A2	VERGEZ et al.	05-15-2003		
JH		WO	03/063833	A1	PERLMAN et al.	08-07-2003		

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## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 6 of 7

<b>Application Number</b>	10/606,575
<b>Filing Date</b>	06/26/2003
<b>First Named Inventor</b>	EDGREN et al.
<b>Group Art Unit</b>	1615
<b>Examiner Name</b>	
<b>Attorney Docket Number</b>	AR03234

## U.S. PATENT DOCUMENTS

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[illegible]

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**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet 7 of 7

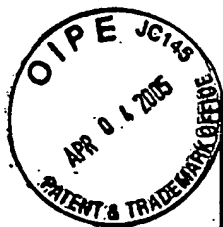
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Filing Date	June 26, 2003
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Group Art Unit	1615
Examiner Name	Not yet assigned
Attorney Docket Number	AR03234

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS			
Examiner's Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITOL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and-or country where published	T <sup>2</sup>
<i>Ja</i>		Encyclopedia of Polymer Science and Technology, "Cellulose Esters, Organic," 3:325-354, Interscience Publishers, NY, 1964	
<i>↑</i>		Klaus Florey Ed., Analytical Profiles of Drug Substances, 13:425, Academic Press, New York, 1984.	
		BASF Technical Bulletin "PLURONIC® and PLURONIC® R Block Copolymer Surfactants" BASF Corporation, 1998-2003.	
		BASF Technical Bulletin "TETRONIC® and TETRONIC® R Block Copolymer Surfactants" BASF Corporation, 1998-2003.	
		Scott & Roff, Handbook of Common Polymers, CRC Press., Cleveland Ohio, 1971.	
		Larry Hixon, et al., "Sizing Materials by Crushing and Grinding", Chemical Engineering, 94-103, November 1990.	
		Eugene L. Parrott, "Milling of Pharmaceutical Solids", Journal of Pharmaceutical Sciences, 61(6):813-829, 1974.	
		Perry's Chemical Engineers Handbook, Perry, Green & Maloney Editors, et al, 6th Ed., "Introduction to Screening and Wet Classification", pp. 21.13 to 21.19, 1984..	
		Remington's Pharmaceutical Sciences, 18th Ed, Ch 91, "Sustained-Release Drug Delivery Systems: Oral Dosage Forms" pp.1682-1685, 1990.	
		Remington's Pharmaceutical Sciences, 17th Ed, Ch. 89, "Powders," pp. 1585-1594, 1985.	
		Physician's Desk Reference, Medical Economics-Thompson Healthcare, 56th Ed., "TOPAMAX®," pp. 2590-2595 and "Dilantin-125"p. 2626, 2002.	
		Giancarlo Santus & Richard W. Baker, "Osmotic drug delivery: a review of the patent literature," Journal of Controlled Release, 35:1-21, 1995.	
<i>✓</i>		Dale E. Wurster, "Air-Suspension Technique of Coating Drug Particles", J. Am. Pharm. Assoc, 48(8):451-454, August 1959.	
<i>Ja</i>		Dale E. Wurster, "Preparation of Compressed Tablet Granulations by the Air-Suspension Technique II", J. Am. Pharm. Assoc, 49(2):82-84, February 1960.	

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SUBMISSION UNDER MPEP 609 D  Page 1 of 1	Application Number	10/606,575
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	Group Art Unit	1615
	Examiner Name	
	Attorney Docket Number	AR03234-USA-NP

## U.S. PATENT DOCUMENTS

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HJA		D. Edgren et al.	USSN 10/606575		
		I. Reyes et al.	USSN 10/910,040		
		N. Yam et al.	USSN 10/920,934		
		N. Modi et al.	USSN 10/930,917		
		D. Edgren et al.	USSN 11/024,329		
		D. Edgren et al.	USSN 11/024,330		
HJA		D. Edgren et al.	USSN 11/024,378		

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